REMARKS/ARGUMENTS

Application Amendments

By the amendments presented, Claim 1 is rewritten to characterize the peptide substrate which is employed in the claimed method as being "surface-attached," i.e., attached or anchored to a surface of a biosensor. Support for addition of this phrase to Claim 1 can be found in the originally filed specification at Page 12, lines 15-16, from Page 12, line 33 to Page 13, line 6, and in Example 4 from Page 20, line 21 to Page 22, line 15 wherein attachment of the peptide substrate to various biosensor surfaces is extensively disclosed.

Also by the amendments presented, Claims 8 and 11 are rewritten to specify that the surface to which the peptide substrate is attached forms part of a solid support and that such a surface will comprise a polymer, a membrane, a resin, a glass or a sponge. Support for these amendment to Claims 8 and 11 can be found in the originally filed specification, for example, at Page 13, lines 2-3.

Upon entry of the claim amendments presented, Claims 1 - 12 remain in the application. No additional claims fee is due as a result of these claim amendments.

Invention Synopsis

The present invention as now claimed is directed to a method for detecting the presence or absence of a bacterium in a sample which can be a wound surface or a body fluid or other fluid taken from a wound. Detection of the presence or absence of the bacterium makes it possible to detect or diagnose infection of the wound with a broad spectrum of pathogenic microorganisms.

In the first step of this method, the sample is contacted with a surface-attached, detectably labeled synthetic α1-proteinase inhibitor reactive site loop domain peptide substrate under conditions that result in cleavage of the substrate by an enzyme produced in the sample by a bacterium. In the second step of the method, cleavage or an absence of the cleavage of the substrate is detected with the cleavage of the substrate indicating the presence of the bacterium in the sample and absence of the cleavage of the substrate indicating absence of the bacterium in the sample.

In preferred invention embodiments, detection of cleavage or no cleavage of the peptide substrate is effected by labeling the substrate with a label such as a spin label, antigen tag, epitope tag, hapten, enzyme label, prosthetic group, fluorescent material, pH-sensitive material, chemiluminescent material, colorimetric component, bioluminescent material, and/or radioactive material. The surface to which the peptide substrate is attached or anchored is also preferably a polymer, membrane, resin, glass or sponge and is associated with a solid support such as a wound dressing, a container for holding body fluids, a disk, a scope, a filter, a lens, a foam, a cloth, a paper, a suture, a dipstick, a swab, a urine collection bag, a blood collection bag, a plasma collection bag, a test tube, a catheter, and/or a well of a microplate.

Formal Matters

In the April 7, 2009 Final Office Action, the Examiner has maintained the rejection of Claims 1-12 under 35 U.S.C. §112, First Paragraph, as allegedly being insufficiently supported by the written description with respect to the detection of the presence or absence of bacteria in the wound sample by means of detecting the presence or absence of enzymes released by the bacteria. The Examiner contends, citing WO 03/040406, that enzymes, such as metalloproteinases (MMPs) which also cleave the specified peptide substrates, are released from neutrophils and macrophages during wound infection/healing. The Examiner thus urges that such metalloproteinases would also be detected by the claimed method, thereby "confounding" use of the method to detect presence or absence of pathogenic wound-infecting bacteria. The Examiner further urges that the specification examples illustrating the method of Claims 1-12 fail to provide enough information about the wounds being investigated and nature of the bacteria therein to teach the skilled artisan how to practice the bacterium detection method of rejected Claims 1-12. Such a rejection is respectfully traversed as it would apply to the amended claims presented herein.

In response to the Examiner's position concerning the Section 112 rejection of Claims 1-12, applicants are submitting herewith the Declaration Under 37 CFR §1.132 of Mitchell C. Sanders, one of the inventors named in the present application. In connection with this Rule 132 Declaration, applicants are also submitting copies of a paper for proposed publication entitled "Rapid Measurement of Protease Activity Prevalent in Bacteria from Wounds: A Diagnostic for

Care Dressing". (An originally signed version of this Declaration will be submitted supplementally.)

Based on the information provided in the Sanders Rule 132 Declaration and in the accompanying proposed publication and poster, it can be seen that the bacterium detection method of Claims 1-12 as amended herein is highly effective at detecting pathogenic bacteria present in wounds or wound fluids. It can further be seen that the detection method as claimed does not, in fact, detect host enzymes such MMPs since these higher molecular weight materials are apparently prevented by steric hindrance factors from cleaving the peptide substrates used in the method as claimed. The Examiner's theory, therefore, that the method of Claims 1-12 would be "confounded" by the detection of enzymes present from other than pathogenic bacteria is believed to not be valid. Furthermore, the extensive clinical study documented in the proposed publication provides further evidence of the effectiveness of using bacteria-produced protease as a marker for early detection of wound infection by pathogenic microorganisms.

Given the foregoing considerations, it is submitted that the specification of the present application teaches the skilled artisan in sufficient detail how to prepare the surface-attached, detectably labeled specific peptide substrates of the present invention and how to use such substrates in the claimed bacterium detection method. Accordingly, it can be seen that the bacterium detection method of the present invention is fully supported by the written description of the specification. Continued rejection of the amended claims under 35 U.S.C. §112, First Paragraph, would therefore be improper.

Conclusions

Applicants have made an earnest effort to place their application in proper form and to claim their invention in a manner which is fully supported by the enabling disclosure of the specification. WHEREFORE, reconsideration of this application, entry of the claim amendments presented herein, consideration of the Declaration of Mitchell C. Sanders Under 37 CFR §1.132 and accompanying documentation submitted herewith, withdrawal of the claim rejection under 35 U.S.C. §112, First Paragraph, and allowance of Claims 1-12 as amended, are all respectfully requested.

Any comments or questions concerning this application can be directed to the undersigned at the telephone number given below.

Respectfully submitted,

Date: September 8, 2009

By: _____

George W. Allen
Registration No. 26,143
Attorney for Applicants

Roberts, Mlotkowski, Safran & Cole, P.C.
7918 Jones Branch Drive, Suite 500
McLean, VA 22102
Telephone: (703) 584-3274
Facsimile: (703)-848-2981